REMARKS

Claims 23-35, 38, 41-47, and 49-79 are pending. Claim 23 is amended herein. Support for the amendments is found throughout the Specification and claims, as filed, and no new matter is presented by the amendment.

Favorable reconsideration in light of the amendments are remarks which follow a respectfully requested.

I. 35 U.S.C. §102 Rejections

Palasis et al.

Claims 23, 24, 27-31, 38, 49, 51, 52, 54, 60, 61, 63, 64, 65, 67, and 79 are rejected under 35 U.S.C. §102(e) over Palasis et al. (USPN 6,969,371). Applicants respectfully traverse.

Claim 23

Applicants claim in claim 23, a method for treating an eye comprising inserting into an eye a device comprising a piercing member having a proximal end and a distal end and a lumen defined therebetween, and a cannula slidably disposed within the lumen, wherein the step of inserting the device into the eye comprises penetrating the eye with the piercing member and advancing the piercing member through the eye, advancing the cannula through the piercing member lumen towards a treatment site, piercing the treatment site with the cannula, and treating the eye by administering and/or aspirating material through the cannula.

Palasis et al. describes a device for delivering fluid into heart tissue. The device includes a primary penetrating member 24 and secondary penetrating members 26. Palasis et al.'s device is specifically designed so as to address problems associated with retention of the fluid in the heart tissue, and does so by utilizing a laterally directed needle which delivers fluid to the heart tissue (col. 3, lines 1-3). In particular, a primary penetrating member penetrates the heart tissue in a first direction, and the secondary penetrating member penetrates the heart tissue in a second direction different from the first direction. According to Palasis, penetration of the tissue in a different direction by the secondary penetrating member reduces fluid leakage from the injection site (col. 3, lines 7-17).

The secondary penetrating members 26 are disposed adjacent the distal end of the primary penetrating member 24 and extend through apertures through the wall of the primary penetrating member (col. 4, lines 49-51 and 63-65). These apertures have an axis at an angle with the longitudinal axis of the primary penetrating member (col. 4, lines 65-67).

Clearly, Palasis et al. at least fails to teach or suggest a method wherein a device comprising a piercing member having a proximal end and a distal end and a lumen defined therebetween, and a cannula slidably disposed within the lumen is inserted into the eye, and the cannula through the piercing member lumen (which extends between the proximal end and distal end of the piercing member and, thus movement of the cannula is in a distal-to-proximal and proximal-to-distal direction within the lumen) towards a treatment site, as set forth by Applicants' claim 23.

Rather, Palasis et al. specifically requires a device having a primary penetrating member with apertures (the apertures having an axis at an angle with the longitudinal axis of the primary penetrating member) extending through the wall of the primary penetrating member. Palasis et al requires a method wherein the heart tissue is penetrated in a first direction with the primary penetrating member and in a second direction different from the first direction with the secondary penetrating members by passing the secondary penetrating members through the angled apertures and through the wall of the primary penetrating member.

Accordingly, claim 23 is patentable over Palasis et al. Claims 24-26, 38, 41-47, 74, 77, and 78 depend from claim 23 and, likewise, are patentable over Palasis et al. Reconsideration and withdrawal of the rejection is respectfully requested.

Claim 27

Applicants claim, in claim 27, a method of treating an eye, comprising piercing the eye with a piercing member and inserting the piercing member into the vitreous humor of the eye, the piercing member having a proximal end and a distal end and a lumen defined therebetween,

angling the piercing member in any direction so as to guide the cannula to any treatment site within the eye, advancing a cannula through the piercing member lumen and beyond the distal end of the piercing member, guiding the cannula through the vitreous humor of the eye to the treatment site, and treating the treatment site.

As set forth above with respect to claim 23, Palasis et al. at least does not teach or suggest a method wherein a piercing member having a proximal end and a distal end and a lumen defined therebetween is inserted into the eye, and the cannula advanced through the piercing member lumen (which extends between the proximal end and distal end of the piercing member). Further, nothing in Palasis et al. teaches or suggests a method wherein the piercing member is angled in any direction after it is inserted into the vitreous humor so as to guide the cannula to any treatment site within the eye. Rather, this teaching comes purely from Applicant.

Accordingly, claim 27 is patentable over Palasis et al. Claims 28-35, 49-59, 75, and 79 depend from claim 27 and, likewise, are patentable over Palasis et al. Reconsideration and withdrawal of the rejection is respectfully requested.

Claim 60

Applicants claim, in claim 60, a method for treating an eye comprising inserting into an eye a device comprising an outer member having a proximal end and a distal end, a cannula slidably disposed within the outer member, and a piercing member at the distal end of the outer member, wherein the step of inserting the device into the eye comprises piercing the eye with the piercing member and advancing the piercing member and at least a portion of the outer member into the eye, advancing the cannula through the outer member and beyond the distal end to the treatment site, and treating the eye by administering and/or aspirating material through the cannula.

As set forth above with respect to claims 23 and 27, Palasis et al. at least does not teach or suggest a method wherein a piercing member pierces the eye and is advanced into the eye, followed by advancing a cannula through the outer member and beyond the distal end of the

outer member. Rather Palasis et al. specifically requires that the primary penetrating member penetrates tissue in a first direction, followed by secondary penetrating members passing through the wall of the penetrating member via apertures angled from the longitudinal axis of the first penetrating member.

Accordingly, claim 60 is patentable over Palasis et al. Claims 61-73 and 76-78 depend from claim 60 and, likewise, are patentable over Palasis et al. Reconsideration and withdrawal of the rejection is respectfully requested.

Cupler, II

Claims 23-35, 38, 42-47, 49-52, 55-65, and 70-77 are rejected under 35 U.S.C. §102(b) over Cupler, II (USPN 4,002,169). Applicants respectfully traverse.

Claim 23

Applicants respectfully submit that Cupler, II does not teach or suggest method for treating an eye comprising inserting into an eye a device comprising a piercing member and a cannula slidably disposed within the piercing member, wherein the step of inserting the device into the eye comprises penetrating the eye with the piercing member and advancing the piercing member through the eye followed by advancing the cannula through the piercing member and piercing the treatment site with the cannula.

Culper, II describes an instrument having a needle 116 with a bore 120 therethrough (col. 6, lines 14-25). A spiral fluted drill 124 is telescoped within the bore 120 (col. 6, lines 30-32). A rotary tool 132 can be substituted for drill 124 (col. 6, lines 42-43) or hollow spiral fluted drill 150 (col. 9, lines 41-44). Thus, Cupler, II's needle 116 (having end 118) is compared to Applicants' penetrating member, while Culper, II's drill 124/hollow drill 150 or rotary tool 132 (having shank 140) is compared to Applicants' cannula.

However, according to Culper, II, the instrument fitted with the drill 124/150 is placed against the cornea with the drill being rotated, and the drill is extended and the instrument moved

inwardly (col. 7, lines 57-62) as the drill augers its way into the eye (col. 8, lines 4-5). After passing through the corna, the lens is then penetrated in a similar manner (i.e. with drill).

Thus, it is clear that Culper, II at least fails to teach or suggest a method for treating the eye wherein the step of inserting the device into the eye comprises penetrating the eye with the "piercing member" (the needle 116) and advancing the "piercing member" (needle 116) through the eye followed by advancing the "cannula" (drill 124/150 or rotary tool 132) through the "piercing member" (needle 116) and piercing the treatment site with the "cannula" (drill 124/150 or rotary tool 132). Rather, Culper, II's "cannula" (drill 124/150) performs both of these penetrating and piercing steps.

Accordingly, claim 23 is patentable over Culper, II. Claims 24-26, 38, 41-47, 74, 77, and 78 depend from claim 23 and, likewise, are patentable over Culper, II. Reconsideration and withdrawal of the rejection is respectfully requested.

Claim 27

As set forth above with respect to claim 23, Culper, II at least fails to teach or suggest a method wherein a piercing member pierces the eye and is inserted into the vitreous humor of the eye and, thereafter, a cannula is advanced through the piercing member lumen to the treatment site.

Further, Applicants respectfully submit that Culper, II does not teach or suggest a method wherein after the "piercing member" (needle 16) is inserted into the vitreous humor of the eye, the "piercing member" (needle 116) is angled in any direction so as to guide the "cannula" (drill 124/150 or rotary tool 132) to any treatment site within the eye. There is nothing in the Culper, II reference regarding angling the "piercing member" (needle 116) after it is inserted within the vitreous humor of the eye.

Accordingly, claim 27 is patentable over Cupler, II. Claims 28-35, 49-59, 75, and 79 depend from claim 27 and, likewise, are patentable over Josephberg. Reconsideration and withdrawal of the rejection is respectfully requested.

Claim 60

As set forth above with respect to claim 23, Culper, II at least fails to teach or suggest a method wherein a piercing member pierces the eye and is inserted into the vitreous humor of the eye and, thereafter, a cannula is advanced through the piercing member lumen to the treatment site.

Accordingly, claim 60 is patentable over Cupler, II. Claims 61-73 and 76-78 depend from claim 60 and, likewise, are patentable over Culper, II. Reconsideration and withdrawal of the rejection is respectfully requested.

2. 35 U.S.C. 103 Rejections

Cupler II, Paques et al., and Bowman et al.

Claims 23-35, 38, 41-47, and 49-79 are rejected under 35 U.S.C. 103(a) over Cupler II, Paques et al. (US Pub 2003/0171722), and Bowman et al. (USPN 6,378,526). Applicants respectfully traverse.

Claim 23

As set forth above with respect to claim 23, Paques et al. at least fails to teach or suggest a method wherein a device (comprising a piercing member having a proximal end and a distal end and a lumen defined therebetween and a cannula slidably disposed within the lumen) is inserted into the eye by penetrating the eye with the piercing member, and advancing the cannula through the piercing member towards a treatment site. Paques' cannula is not slidably disposed within a lumen between the proximal end and distal end of the piercing member, and the cannula is not advanced through such a lumen towards a treatment site after penetrating the eye with the piercing member.

Culper, II does not remedy these deficiencies. According to Culper, II, the "cannula" (drill 124/150) is used to auger its way into the eye. The "cannula" (drill 124/150), likewise, augers its way into the lens (treatment site). Culper, II does not teach or suggest a method wherein an outer "piercing member" (needle 116) penetrates the eye, followed by advancing the "cannula" (drill 124/150 or rotary tool 132) through the "piercing member" (needle 116) lumen and piercing the treatment site with the "cannula" (drill 124/150 or rotary tool 132). Rather, Culper, II's "cannula" (drill 124/150) performs both of these penetrating and piercing steps.

Further, Bowman et al. does not remedy these deficiencies. Bowman et al. is cited for the delivery of steroids, genetic material, or pharmaceuticals to the eye. However, Bowman et al. does not teach or suggest the device or method set forth in claim 23.

Thus, no combination of Cupler, II, Palasis et al., and Bowman et al. teach or suggest applicants' claim 23. Accordingly, claim 23 is patentable over Cupler, II, Palasis et al, and Bowman et al. Claims 24-26, 38, 41-47, 74, 77, and 78 depend from claim 23 and, likewise, are patentable over Cupler, II, Palasis et al, and Bowman et al. Reconsideration and withdrawal of the rejection is respectfully requested.

Claim 27

As set forth above, Palasis et al. at least does not teach or suggest a method wherein a piercing member having a proximal end and a distal end and a lumen defined therebetween is inserted into the eye and the cannula advanced through the piercing member lumen beyond the distal end of the piercing member. Further, nothing in Palasis et al. teaches or suggests a method wherein the piercing member is angled in any direction after it is inserted into the vitreous humor so as to guide the cannula to any treatment site within the eye. Rather, this teaching comes purely from Applicant.

Cupler, II does not remedy these deficiencies. Culper, II at least fails to teach or suggest a method wherein a piercing member pierces the eye and is inserted into the vitreous humor of the eye and, thereafter, a cannula is advanced through the piercing member lumen to the

treatment site. Further, nothing in Culper, II teaches or suggests a method wherein the piercing member is angled in any direction after it is inserted into the vitreous humor so as to guide the cannula to any treatment site within the eye. Rather, this teaching comes purely from Applicant.

Further, Bowman et al. does not remedy these deficiencies. Bowman et al. is cited for the delivery of steroids, genetic material, or pharmaceuticals to the eye. However, Bowman et al. does not teach or suggest the device or method set forth in claim 27.

Accordingly, claim 27 is patentable over Cupler, II, Palasis et al, and Bowman et al. Claims 28-35, 49-59, 75, and 79 depend from claim 27 and, likewise, are patentable over Cupler, II, Palasis et al, and Bowman et al. Reconsideration and withdrawal of the rejection is respectfully requested.

Claim 60

As set forth above, Palasis et al. at least does not teach or suggest a method wherein a piercing member pierces the eye and is advanced into the eye, followed by advancing a cannula through the outer member and beyond the distal end of the outer member.

As set forth above, Cupler, II at least does not teach or suggest a method wherein a piercing member pierces the eye and is inserted into the vitreous humor of the eye and, thereafter, a cannula is advanced through the piercing member lumen to the treatment site.

Further, Bowman et al. does not remedy these deficiencies. Bowman et al. is cited for the delivery of steroids, genetic material, or pharmaceuticals to the eye. However, Bowman et al. does not teach or suggest the device or method set forth in claim 27.

Accordingly, claim 60 is patentable over Cupler, II, Palasis et al, and Bowman et al. Claims 61-73 and 76-78 depend from claim 60 and, likewise, are patentable over Cupler, II, Palasis et al, and Bowman et al. Reconsideration and withdrawal of the rejection is respectfully requested.

CONCLUSION

Applicant respectfully requests early consideration and allowance of the subject application.

Applicants believe that additional fees are not required in connection with the consideration of the within matter. However, if for any reason a fee is required, a fee paid is inadequate or credit is owed for any excess fee paid, you are hereby authorized and requested to charge Deposit Account No. **04-1105.**

Should the Examiner wish to discuss any of the amendments and/or remarks made herein, the undersigned attorney would appreciate the opportunity to do so.

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Respectfully submitted,

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